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of the Food Safety Authority of Ireland

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FSAI Risk Ranking Model for Chemical Contaminants in Food

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GLOSSARY

BIM: Bord Iascaigh Mhara

BMD: the benchmark dose is based on a mathematical model being fitted to the experimental data within the observable range and estimates the dose that causes a low but measurable response (the benchmark response (BMR)) typically chosen at a 5% or 10% incidence above the control.

BMDL: benchmark dose lower limit (see BMD). The BMD lower limit (BMDL) refers to the corresponding lower limits of a one-sided 95% confidence interval on the BMD. Using the lower limit takes into account the uncertainty inherent in a given study, and assures (with 95% confidence) that the chosen BMR is not exceeded.

Bw: body weight

Carcinogenic: causing cancer

DAFM: Department of Agriculture, Food and the Marine

$E_{\%HBGV}$: percentage contribution to the (indicative) HBGV from exposure to a contaminant in a foodstuff

EC: European Community

EFSA: European Food Safety Authority

EHS: Environmental Health Service

EPA: Environmental Protection Agency

$E_{Tot\%HBGV}$: overall contribution to the (indicative) HBGV from exposure to a contaminant from all foods

EU: European Union

FAO: Food and Agriculture Organization

FSAI: Food Safety Authority of Ireland

FSLS: Food Safety Laboratory Service. The FSLS comprises three PALs.

GEMAS: Geochemical Mapping of Agricultural and Grazing Land Soils of Europe

HBGV: health-based guidance value

IGFA: Irish Grain and Feed Association

JECFA: The Joint FAO/WHO Expert Committee on Food Additives

Kg: kilogram

MCDA: multi-criteria decision analysis

mg: milligram = 10^{-3} part of a gram (0.001 g)

MI: Marine Institute

MoE: margins of exposure (MoEs) are calculated by dividing the BMDL values derived from dose-response data for the different endpoints by the estimates of dietary exposure

µg: microgram = 10^{-6} part of a gram (0.000001 g)

NANS: National Adult Nutrition Survey

NCFS: National Children's Food Survey

NFSS2: National Food Safety Surveillance database, version 2

ng: nanogram = 10^{-9} part of a gram (0.000000001 g)

PALs: Public Analyst's Laboratories

POD: point of departure

SCF: Scientific Committee on Food

SET: (exposure score) x (toxicity score)

SFPA: Sea-Fisheries Protection Authority

SP: policy flag

TDI: tolerable daily intake

TDS: Total Diet Study

TOR: terms of reference

CHAPTER 1. BACKGROUND INFORMATION

The Food Safety Authority of Ireland (FSAI) has national responsibility for coordinating the enforcement of food safety legislation in Ireland. One aspect of enforcement is sampling and analysis of products on the Irish market and comparison of analytical results with legislative maximum levels.

The National Chemical Monitoring Programme is reviewed on an annual basis and agreed between the FSAI, the Environmental Health Service (EHS), and the Food Safety Laboratory Service (FSLS). The FSLS comprises three Public Analyst's Laboratories (PALs). The plan incorporates a broad range of parameters, including mycotoxins and other natural contaminants, heavy metals, food processing contaminants, food contact materials, food additives and flavourings, and some quality parameters.

Each year, the FSAI prepares a proposal which feeds into the development of the programme.

The proposal is currently based on the following factors:

- Legislative requirements
- Risk to consumers
- Non-compliance rate
- Current focus of priorities at EU level
- Rapid Alert System for Food and Feed (RASFF) alerts
- Emerging issues
- Findings by the European Commission Directorate-General for Health and Food Safety, Health and Food Audits and Analysis division (Directorate F, formerly the Food and Veterinary Office).

The FSAI is currently considering the concept of applying a formalised 'risk ranking' approach to sampling for the National Chemical Monitoring Programme. Different models for risk ranking exist and need to be reviewed with a view to establishing a starting point. Implementation of a risk ranking approach may aid in the efficient and effective deployment of available resources, and shift focus to areas of most concern to Irish consumers.

The FSAI Scientific Committee was asked to consider the appropriateness of applying a risk ranking approach to sampling for chemical contaminants in food and to develop a suitable model. In particular, the Committee was required to answer the following question: What is the most appropriate risk ranking system for prioritising selection of food/chemical analyte combinations for the annual national official controls testing programme, and what information and data are required to develop and implement the risk ranking system?

Terms of Reference

The terms of reference (TOR) for this work required a review of existing risk ranking systems, with the purpose of identifying or building on the most suitable model for Ireland. The intended scope and coverage of the system was to be discussed, and benefits and limitations of including specific parameters above the recommended core criteria were to be highlighted. In particular, consideration was to focus on the inclusion of parameters such as national food production (volumes), food import/export, regional characteristics, environmental factors and specific food processing factors/food handling techniques.

CHAPTER 2. INTRODUCTION

A draft opinion was prepared for the Scientific Committee by the Chemical Safety Subcommittee, which formed a Risk Ranking Working Group. The working group in turn established two focus groups: the Risk Ranking Model Focus Group and the Toxicological Focus Group (see Acknowledgments p. 22). The Risk Ranking Model was developed by the Risk Ranking Working Group, with input from the two focus groups.

This document recommends an approach to be used for ranking the analysis of chemicals in foodstuffs on a risk basis, but cannot be used to draw inferences about the safety of foodstuffs considered.

CHAPTER 3. METHODOLOGY

3.1 Scope of the risk ranking system

In accordance with the TOR, the Risk Ranking Working Group discussed the intended scope of the project and at the outset considered the inclusion of parameters such as non-compliance rates, national food production (volumes), food import/export data, regional/geographical characteristics, environmental factors and specific food processing/ food handling techniques.

At an early stage in the development of the project, it was agreed that the scope of the exercise should be limited to chemical contaminants only in the first instance. This was due to the large number of chemical contaminants currently included in the National Chemical Monitoring Programme, coupled with the fact that other chemicals, such as additives and flavourings, are already risk assessed before they are approved for use in foods. The list of chemical contaminants to be covered by this risk ranking approach is outlined in Appendix I. It was decided to pilot the approach using four chemicals: cadmium, acrylamide, aflatoxin B1 and fumonisin B1.

The following sections discuss the feasibility of incorporating the parameters mentioned above.

3.1.1 Non-compliance rates

The results from the National Chemical Monitoring Programme are stored in the FSAI National Food Safety Surveillance database (NFSS2). The food group classification systems used for these data were found to be incompatible with the food group classification system used for the FSAI Total Diet Study (TDS) (FSAI, 2016), which was incorporated into the model (Section 4.1). In addition, for a number of the chemicals included in the Chemical Monitoring Programme, only a small number of samples are routinely tested annually. Therefore, any inferences made from these results may not be representative of the picture for the whole food group. Furthermore, the inclusion of non-compliance rates, which are not available for all contaminant/foodstuff combinations, was considered to introduce bias towards those for which results are available.

Therefore, it was decided not to include non-compliance rates in the model. However, by identifying and flagging trends in non-compliance rates, such information will continue to be considered in drawing up the annual National Chemical Monitoring Programme.

3.1.2 National food production volumes/Food import and export data

Information on cereal imports and exports was obtained from the Irish Grain and Feed Association (IGFA). Irish harvest and production figures for cereals were obtained from the Department of Agriculture, Food and the Marine (DAFM), and Teagasc, respectively. Information on seafood imports and exports, as well as aquaculture production broken down by species, was obtained from Bord Iascaigh Mhara (BIM). Furthermore, information on seafood landings by Irish vessels into Irish ports, broken down by species, was provided by the Sea-Fisheries Protection Authority (SFPA). The Environmental Health Service (EHS) provided data on the types of foods handled by manufacturers under their remit, as well as information on the number of Irish manufacturers of alcoholic drinks, food supplements, packaged water and food ingredients. Information on spice imports from India and from other non-specified countries was also obtained from Revenue. A number of spices from India, Indonesia, and Ethiopia are subject to special import control measures laid down in Commission Implementing Regulation (EU) No 884/2014 (as amended). Revenue had no returns for spice imports into Ireland from Indonesia and Ethiopia. Production figures for foods of animal origin were obtained from the National Residue Monitoring Programme.

The integration of the supplied information into the risk ranking approach was considered difficult to implement in practice, as the data were not representative of the full range of foodstuffs considered in the model, and it was difficult to relate the production data based on raw food commodities to food as consumed. There were also some discrepancies in the data for cereals provided from different sources (due to different collection criteria), and limited

information was obtained on the ultimate destination of these cereals, i.e. for food or feed use. Information provided indicated that approximately 90% of Irish fishery landings were most likely exported to other EU countries for consumption. The non-exhaustive nature of the data, the presence of inconsistencies between data sources, and the incompatibility of the data with food consumption data and legislative categories prevented the data from being integrated into the risk ranking approach. However, this type of information can be utilised in a qualitative manner when drawing up the National Chemical Monitoring Programme.

3.1.3 Regional characteristics/environmental factors

Geochemical maps, such as the *Soil Geochemical Atlas of Ireland* (EPA, 2018), map the occurrence of several elements in soils throughout Ireland. International data can be used to provide information on the occurrence of soil-based contaminants in food. For example, the European project Geochemical mapping of agricultural and grazing land soils of Europe (GEMAS)[1] provides comprehensive data on the occurrence of several elements in soil throughout Europe.

However, regional characteristics/environmental factors could not be integrated into the risk ranking system due to the unavailability of data for the wide range of contaminant/foodstuff combinations which were, and will be, considered. For these data to be used in the risk ranking approach, they would need to be converted to a useable format, i.e. contaminant level in food. The scarcity of information on the uptake of these elements from soil to individual food crops, and the limited scope of contaminants covered, make their inclusion into the risk ranking approach itself impractical. This type of information has been incorporated into the National Chemical Monitoring Programme for a select number of contaminants (e.g. cadmium, lead) and more systematic incorporation of this information, for example in a qualitative manner, such as in a flagging system, could be considered in the future.

3.1.4 Food processing factors/food handling techniques

Initially, food processing factors and food handling techniques were considered for inclusion in the risk ranking approach. Processing factors are applied to the level of the contaminant in the raw unprocessed commodity in order to derive a corresponding level in food as consumed. Processing can potentially lead to an increase or a decrease in the level of the contaminant, depending on the specific processing conditions and physicochemical properties of the substance in question.

Processing factors would be particularly important for the ranking of process contaminants and would be useful to identify the most important food manufacturing steps responsible for their formation, e.g. frying of potato chips to form acrylamide. Similarly, food handling information would be useful to identify the most important steps responsible for the introduction of contaminants into food, e.g. cross-contamination of food with mineral oils due to transport in recycled cardboard boxes. Processing factors and food handling information would have to be determined for each contaminant/foodstuff combination which, due to the timelines set for the development of the risk ranking approach and the large number of contaminant/foodstuff combinations involved, precluded this aspect from being incorporated into the model at this stage.

The proposed risk ranking approach used exposure values estimated as part of the 2012–2014 FSAI TDS (FSAI, 2016). In carrying out a TDS, the most commonly consumed foods in Ireland, based on food consumption data, are analysed for particular chemical contaminants, food additives and nutrients present in the food as consumed (e.g. grilled, fried, etc.). Dietary exposure to each chemical is then estimated using the Irish food consumption data and the level of the particular chemical present in each food. The food consumption data used in the FSAI 2012–2014 TDS were derived from the National Adult Nutrition Survey (NANS) (IUNA, 2011), and the National Children's Food Survey (NCFS) (IUNA, 2005). The data from these consumption surveys and the occurrence data for the various contaminants tested in foods prepared ready for consumption were combined to calculate the exposure. As a result,

[1] see https://data.gov.ie/dataset/gsi-gemas-european-geochemical-data

food processing and food handling information was not required for the proposed risk ranking approach as this information was accounted for in the TDS exposure estimates.

However, for chemical/foodstuff combinations not considered by the TDS, occurrence data and consumption data may need to be combined in the future, which could necessitate the incorporation of processing factors/handling techniques for certain contaminant/foodstuff combinations. Therefore, although processing factors and information on food handling techniques were not included as a ranking parameter in the proposed approach, a database of this information could be created and incorporated in the future. The processing factors could also be used to add further detail to the ranking of some contaminants in food. For example, a processing factor for the effect of roasting coffee on acrylamide formation would allow the risk from exposure to dark roast coffee to be differentiated from light roast coffee.

The collection of processing factors/food handling information will be determined based on the type of exposure data utilised in the Risk Ranking Model in the future. The integration of food consumption data and chemical concentration data for foodstuffs at different stages of production will necessitate the incorporation of such information. If TDS data are deemed to be the most suitable, then the scope of future TDSs might have to be changed in order to facilitate use of such data in the risk ranking approach.

Although the parameters discussed in Sections 3.1.1–3.1.4 were not incorporated into the risk ranking approach that was developed, there may be an opportunity to incorporate some of these aspects in the future. This will depend on the considerations detailed above (e.g. source of dietary exposure data utilised in the future or availability of more robust, compatible and complete data).

As outlined above, the incorporation of information relating to non-compliance rates, regional characteristics, food processing factors or handling techniques, etc. is in many cases already being used to inform the final selection of contaminant/foodstuff combinations for the National Chemical Monitoring Programme, which is developed on an annual basis.

3.2 Risk ranking approach

A number of publications were considered when deciding on a suitable risk ranking approach (Barlow *et al.*, 2015, Newsome *et al.*, 2009, Sand *et al.*, 2015, Hanlon *et al.*, 2015, EFSA BIOHAZ Panel, 2015, van der Fels-Klerx *et al.*, 2015). From this literature review, particularly the publication of van der Fels-Klerx *et al.*, 2015, a number of approaches to risk ranking were identified as potentially suitable, such as expert judgement, risk matrix, risk ratio (exposure/effect), multi-criteria decision analysis (MCDA), flow charts/decision trees and scoring methods.

Expert judgement, on its own, was considered to be unsuitable because it is both time and resource intensive. The risk matrix approach has the drawback of being qualitative or semi-quantitative and is, therefore, less accurate than methods based on concentration data and dose-response relationships or toxicological reference values. A disadvantage of the risk ratio method is that it is difficult to apply such methodology to emerging risks. Disadvantages of the MCDA approach are that (a) the outcome is more difficult to communicate than more straightforward methods, such as risk matrices or scoring methods, as various criteria are included, each having different weights, and (b) the MCDA method also requires expert or stakeholder input in order to derive the weights for the criteria. Risk ranking using flow charts/decision trees are based on a set of clearly defined questions or criteria by which the chemical hazards can be classified into different categories (high, medium or low) for their risk to human health. This type of method depends strongly on expert input and is less transparent than the other methods.

Given that the available data for risk ranking are food consumption data, chemical residue occurrence data and chemical toxicity data, supported by expert judgement, a scoring method was considered to be the most appropriate approach.

CHAPTER 4. PROPOSED RISK RANKING MODEL

The core elements of exposure, hazard and legislation were identified for inclusion in the ranking methodology, as shown in Table 1.

Table 1. Core elements used in the risk ranking methodology

Core elements	Input parameters	Model component
Exposure data	• Irish food consumption data • Concentration data for the chemicals under consideration	Exposure score
Hazard data	Toxicological information on the chemicals under review, including data on any health-based guidance values (HBGVs), benchmark doses (BMDs) or other reference points and the pivotal study that was used to derive such values	Toxicity score
Legislative requirements	Information on whether there were any legislative maximum levels for the chemicals under consideration or whether they were subject to any safeguard measures, increased import control frequency provisions or monitoring recommendations	Policy flag

The following sections outline the components of the proposed FSAI Risk Ranking Model for contaminants.

4.1 Exposure score

The Risk Ranking Working Group considered the availability of food consumption data and possible combination of consumption data with chemical concentration data stored in the national FSAI database to derive the exposure score. However, data gaps exist in the available concentration data, which would introduce bias towards foodstuffs for which such data are available, and would potentially omit foodstuffs for which occurrence data have not yet been gathered. Furthermore, processing factors are required to match chemical concentration data (typically determined in 'food as purchased') with food consumption data (typically reported 'as consumed'). In addition, a harmonised food classification system is required in order to integrate these two datasets. In light of these difficulties, the exposure score was calculated using exposure data from the 2012–2014 TDS (FSAI, 2016).

In the 2012–2014 FSAI TDS, chemical contaminants were analysed in a range of target and non-target foods (141 food groups) as consumed. The exposure was then estimated using probabilistic web-based software (Creme Food). The food consumption data used in the 2012–2014 FSAI TDS were derived from NANS and the NCFS. As the TDS includes foods covering approximately 90% of the typical diet, certain foods, such as niche products, may not be adequately covered. However, this limitation was considered acceptable in comparison to the greater limitation of incompatible datasets, described above.

The exposure score is the summation of two individual scores, which are described in more detail in Sections 4.1.1 and 4.1.2.

$$score_{\%HBGV} + score_{Tot\%HBGV} = \text{exposure score}$$

4.1.1 Percentage contribution to the (indicative) HBGV from exposure to a contaminant in a foodstuff ($E_{\%HBGV}$)

$E_{\%HBGV}$ is the first input into the exposure score and takes into account the relative contribution of an individual foodstuff to the (indicative) HBGV (see Section 4.2) of a chemical, and thereby provides information on the extent of exposure to the chemical via the individual food. This score also facilitates the ranking of relevant foods within a food category contributing to the exposure of the chemical in question. Such ranking allows for prioritisation of foodstuffs which are the highest contributors of exposure towards the HBGV, and control of these foodstuffs is therefore considered to have the greatest impact in terms of reducing exposure (by minimising non-compliance).

$$\frac{\text{Exposure to contaminant A in food A}}{\text{(indicative) health-based guidance value}} \times 100 = \boldsymbol{E_{\%HBGV}}$$

The $E_{\%HBGV}$ is assigned a score ($score_{\%HBGV}$) based on the scale shown in Table 2.

Table 2. Scale used to derive the $score_{\%HBGV}$ exposure score assigned to $E_{\%HBGV}$

% contribution to (indicative) HBGV ($E_{\%HBGV}$)	$score_{\%HBGV}$
<5	0
5<10	3
10<15	6
15<20	9
20<25	12
25<30	15
30<35	18
35<40	21
40<45	24
45<50	27
50<55	30
55<60	33
60<65	36
65<70	39
70<75	42
75<80	45
80<85	48
85<90	51
90<95	54
95<100	57
≥100	60

The choice of this scoring scale is discussed in Section 4.1.2, since it applies to both inputs to the exposure score.

4.1.2 Overall contribution to the (indicative) HBGV from exposure to a contaminant from all foods ($E_{Tot\%HBGV}$)

$E_{Tot\%HBGV}$ is the second input to the exposure score and takes into account the overall status of exposure in relation to an existing (indicative) HBGV. It ranks chemicals according to the extent of exposure. Such ranking allows for prioritisation of chemicals of higher concern, and control of these chemicals is therefore considered to have the highest impact in terms of human health protection.

$$\frac{\text{Exposure to contaminant A in all food}}{\text{(indicative) health-based guidance value}} \times 100 = E_{Tot\%HBGV}$$

The scale for the $E_{Tot\%HBGV}$ is the same as for the $E_{\%HBGV}$, where the highest score of 60 was assigned. In this way, the total exposure score (i.e. the summation of the two exposure score inputs), provides a value of 120, which is equivalent to the total score that can be obtained for the toxicity component (see Section 4.2). A lower value was considered for the highest score of each scale, but a lack of granularity was observed from the generated output. In addition, when the highest score of each scale was reduced, appropriate increments could not be generated without introducing decimals, which would compromise the policy flagging system (see Section 4.3). The increments for each of the scales (i.e. 5%) were chosen after trialling a number of different scenarios using higher and lower increments. Larger increments, such as 10%, did not provide sufficient granularity in the final score for each contaminant/foodstuff combination. The increment of 5% was the highest increment found to give acceptable granularity in the scores, which was necessary to differentiate each contaminant/foodstuff combination in the ranking model.

4.1.3 Exposure score example

For example, six different foods contribute to exposure to chemical A, and two different foods contribute to exposure to chemical B, and are assessed against a HBGV value for each chemical A and chemical B of 50, resulting in $E_{\%HBGV}$ scores as shown in Table 3.

Table 3. Example showing how $score_{\%HBGV}$ is derived

Chemical A				Chemical B			
Food	Exposure	% contribution to HBGV (=50)	$score_{\%HBGV}$	Food	Exposure	% contribution to HBGV (=50)	$score_{\%HBGV}$
Food 1	12	24%	12	**Food 7**	30	60%	36
Food 2	15	30%	18	**Food 8**	5	10%	6
Food 3	36	72%	42				
Food 4	5	10%	6				
Food 5	10	20%	12				
Food 6	20	40%	24				
All foods	98	196%		**All foods**	35	70%	

In this case, based solely on the percentage contribution to the HBGV score, the order of importance of food testing for these two chemicals would be Food 3 > Food 7 > Food 6 > Food 2 > Food 1/Food 5 > Food 4/Food 8.

Total exposure to chemical A from all sources compared with a HBGV of 50 is 196%, and for chemical B is 70%, resulting in $E_{Tot\%HBGV}$ scores as shown in Table 4.

Table 4. Example showing how score$_{Tot\%HBGV}$ is derived

Chemical A				Chemical B			
Food	Exposure	% contribution to HBGV (=50)	score$_{Tot\%HBGV}$	Food	Exposure	% contribution to HBGV (=50)	score$_{Tot\%HBGV}$
All foods	98	196%	60	**All foods**	35	70%	42

In this case, based solely on total exposure from the all foods score, chemical A would be considered more important than chemical B.

Summation of the two derived exposure score inputs ($E_{Tot\%HBGV}$ and $E_{\%HBGV}$) provides an overall exposure score and allows for ranking of the foods in relation to the extent of exposure (see Table 5).

Table 5. Example showing how the overall exposure score is derived

Chemical A				Chemical B			
Food	score$_{\%HBGV}$	score$_{Tot\%HBGV}$	Total score	Food	score$_{\%HBGV}$	score$_{Tot\%HBGV}$	Total score
Food 1	12	60	72	**Food 7**	36	42	78
Food 2	18	60	78	**Food 8**	6	42	48
Food 3	42	60	102				
Food 4	6	60	66				
Food 5	12	60	72				
Food 6	24	60	84				

Finally, based on the exposure score alone, the relative importance of food testing for these two chemicals would be Food 3 > Food 6 > Food 2/Food 7 > Food 1/Food 5 > Food 4 > Food 8.

4.2 Toxicity score

The toxicity scoring matrix (see Table 6) was developed by the Toxicological Focus Group, which comprised members of the Chemical Safety Subcommittee. The toxicity matrix is a compilation of two toxicity scoring systems, one used for veterinary drug residues (Clare and Price, 2012) and the other used for chemical contaminants in food ingredients (Hanlon *et al.*, 2015). The Nature of Hazard and (indicative) HBGV scores are based on the critical effect identified in a Scientific Opinion (e.g. the European Food Safety Authority (EFSA) or Joint FAO/WHO Expert Committee on Food Additives (JECFA)) and the associated HBGV (e.g. tolerable daily intake (TDI)), respectively. Where no HBGV was available, an *indicative* HBGV was calculated using an available critical reference point and by applying an appropriate safety factor. For example, EFSA is of the view that a margin of exposure (MoE) of 10,000 or higher, if it is based on a $BMDL_{10}$ from an animal study, and taking into account overall uncertainities in the interpretation, would be of low concern from a public health point of view and might reasonably be considered as a low priority for risk management actions (EFSA, 2005). Therefore, where a benchmark dose level (BMDL) was available, an indicative HBGV was calculated by dividing the BMDL by a safety factor of 10,000. There are certain scenarios which can influence the safety factor chosen. For example, if the reference point is based on human studies and/or the substance is considered not to be a genotoxic carcinogen, the safety factor is reduced as appropriate (e.g. for BMDLs set for lead, generally MoEs of 10 are considered sufficient).

Table 6. Toxicity matrix

Nature of hazard		(indicative) health-based guidance value (HBGV) (mg/kg bw/day)					
		>10	>0.1–10	>0.001–0.1	>0.00001–0.001	>0.0000001–0.00001	≤0.0000001
Score	**Critical effect**	**10**	**20**	**30**	**40**	**50**	**60**
0	No reported adverse effects.						
10	Reversible pharmacological adverse effects (e.g. increased blood pressure or heart rate). Microbiological effects (e.g. disturbance of the gut flora).						
20	Reversible organ toxicity (e.g. kidney or liver damage).						
30	Irritation. Evidence of allergic reactions in animals.						
40	Carcinogenicity by mechanisms not relevant to humans. Irreversible organ toxicity/foetotoxity/ embryotoxicity/ immunotoxicological effects (e.g. sensitisation).						
50	Mutagenicity. Irreversible neurotoxic effects. Irreversible reprotoxic effects.						
	Evidence of carcinogenicity in humans or carcinogenic by mechanisms relevant to humans.						
60	Genotoxic carcinogen (known to cause cancer by direct effects).						
150	Anaphylactants and acute toxicants.						

The MoE is the ratio of a chosen point of departure (POD) on the dose-response curve for the adverse effect to a human exposure estimate (MoE=POD/exposure) and, therefore, makes no implicit assumptions about a 'safe' intake. Rather, it is used for setting priorities for action, either with regard to urgency or the extent of measures that may be necessary (EFSA, 2005). Therefore, for the purposes of developing a Risk Ranking Model for prioritising the analysis of chemicals in food of potential concern, the calculation of indicative HBGVs, based on reference points such as benchmark doses, was deemed fit for purpose.

The hazard score increments (0–60) and the (indicative) HBGV score increments (10–60) were assigned a proportional weight as applied in the exposure scoring system. In this way, the maximum score that could be calculated for the toxicity score (chronic effects) is 120, which is equivalent to the maximum score that can be obtained from the exposure score (i.e. 120). The (indicative) HBGV score is based on increments of 100. The hazard category "Anaphylactants and acute toxicants" was assigned a higher hazard score of 150 in order to distinguish chemicals which elicit severe acute effects.[2]

The following example outlines the derivation of the toxicity score calculated for aflatoxin B1 using the toxicity matrix:

A $BMDL_{10}$ (10% extra cancer risk) of 170 ng/kg bw/day (0.00017 mg/kg bw/day) was established by EFSA for aflatoxin B1 (EFSA CONTAM Panel, 2007). The $BMDL_{10}$ was derived from a study involving administration of aflatoxin B1 at a range of dietary doses to rats. As noted above, an MoE of 10,000 or higher, if it is based on a $BMDL_{10}$ from an animal study, is considered to be of low concern from a public health perspective (EFSA, 2005). Therefore, the $BMDL_{10}$ was divided by 10,000 in order to align this reference point with HBGVs.

The corrected reference point, $BMDL_{10}$ ÷ 10,000 (0.000000017 mg/kg bw/day), was assigned an (indicative) HBGV score of 60. With respect to the hazard score, aflatoxins are considered to be genotoxic and carcinogenic. Therefore, aflatoxin B1 was assigned a hazard score of 60. The summation of these two scores results in the overall toxicity score of 120 for aflatoxin B1. This is illustrated in Table 7.

[2] Such chemicals are often subject to specific monitoring programmes (e.g. the shellfish toxin monitoring programme for marine biotoxins), or may require more tailored monitoring outside the scope of the National Chemical Monitoring Programme; however, for the purposes of ranking risk, it was deemed appropriate to include them.

Table 7. Example of toxicity matrix score for aflatoxin B1

Nature of hazard		(indicative) health-based guidance value (HBGV) (mg/kg bw/day)					
		>10	>0.1–10	>0.001–0.1	>0.00001–0.001	>0.0000001–0.00001	≤0.0000001
Score	**Critical effect**	**10**	**20**	**30**	**40**	**50**	**60**
0	No reported adverse effects.						
10	Reversible pharmacological adverse effects (e.g. increased blood pressure or heart rate). Microbiological effects (e.g. disturbance of the gut flora).						
20	Reversible organ toxicity (e.g. kidney or liver damage).						
30	Irritation. Evidence of allergic reactions in animals.						
40	Carcinogenicity by mechanisms not relevant to humans. Irreversible organ toxicity/foetotoxity/ embryotoxicity/ immunotoxicological effects (e.g. sensitisation).						
50	Mutagenicity. Irreversible neurotoxic effects. Irreversible reprotoxic effects.						
	Evidence of carcinogenicity in humans or carcinogenic by mechanisms relevant to humans.						
60	Genotoxic carcinogen (known to cause cancer by direct effects).						aflatoxin B1 score (60+60 =120)
150	Anaphylactants and acute toxicants.						

4.3 Policy flag

The policy flag is intended to highlight food/contaminant combinations for which legislative or other monitoring requirements exist, and which need to be considered when drawing up the monitoring programme. Monitoring recommendations, increased import control frequency provisions and safeguard measures imply the explicit need for collating data or monitoring a situation of increased risk. Legislative limits are principally set for contaminants in foods which have been identified as major dietary contributors, or are known to contain elevated levels of such contaminants. Due to the increasing amount of maximum limits for contaminants in foods, the risk ranking approach will allow for prioritisation of those foods which present the greatest risk. Input parameters for the policy flag are outlined in the following sections.

4.3.1 Legislative limits

As the principal function of the National Chemical Monitoring Programme is to test for compliance of foodstuffs with food safety legislation and thereby protect consumers, chemicals for which legislative maximum limits exist need to be highlighted in the risk ranking system. The principal legislation related to chemical contaminants is Commission Regulation (EC) No 1881/2006, setting maximum levels for certain contaminants in foodstuffs, but other pieces of legislation, such as vertical legislation making reference to maximum limits, may apply.

4.3.2 EU monitoring recommendations

Monitoring recommendations are typically issued to generate data where gaps have been identified. The data collected under such recommendations are typically used to inform EFSA Scientific Opinions, to generate robust datasets for the purposes of establishing maximum limits, or to examine prevalence of chemicals in certain foodstuffs. It is necessary, therefore, to flag those contaminants and foods for which specific recommendations apply. For example, the Commission Recommendation on reduction of the presence of cadmium in foodstuffs (2014/193/EU) requires monitoring of cadmium in vegetables and cereals.

4.3.3 Safeguard measures and provisions on increased frequency of controls at import

Special conditions exist governing certain foodstuffs imported from some third countries due to contamination risks, and it is therefore necessary to flag such provisions in the risk ranking system. The following legislation was taken into consideration in the risk ranking approach:

- Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009
- Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC

4.3.4 Emerging risk

Chemicals of potential concern need to be taken into consideration when planning the National Chemical Monitoring Programme. Therefore, such chemicals need to be flagged in the risk ranking system to allow for a robust database to inform risk management measures, as required. A similar system as was assigned to the above policy parameters was used to capture whether the substance in question is considered to be an emerging risk.

4.3.5 Policy flagging system

The above parameters are flagged using a decimal system. In this way, the presence of a policy parameter or a recognised emerging risk is visibly apparent from the generated output of the Risk Ranking Model. Table 8 illustrates the decimal flagging system assigned to policy parameters or an emerging risk.

Table 8. Decimal flagging system assigned to policy parameters or an emerging risk

A. Legislative limit/monitoring recommendation	
Legislative limit	0.1
Monitoring recommendation	0.2
B. Safeguard measures/Increased import control frequency provisions	
Commission Implementing Regulation (EU) No 884/2014	0.01
Commission Regulation (EC) No 669/2009	
C. Emerging risk	
If applicable	0.001
Overall policy flag (A+B+C)	

It can be observed in Table 8 that policy flags are additive. For example, where a legislative limit and a monitoring recommendation are applicable to the contaminant/foodstuff in question, a value of 0.3 is assigned (sum of legislative limit flag and monitoring recommendation flag). In addition, where one or more safeguard/import control measures are applicable to the contaminant/foodstuff in question, an overall value of 0.01 is assigned. Finally, if an emerging risk is considered applicable, a value of 0.001 is added. Consequently, an overall policy flag, where all the conditions above apply, would be the sum of all these flags, i.e. 0.311.

The following are examples of policy flags generated from the risk ranking model.

It can be observed from Table 9 that a policy flag of 0.2 was assigned to acrylamide in breakfast cereals (cornflakes) due to the presence of a monitoring recommendation (2013/647/EU).

Table 9. Acrylamide in cornflakes

Chemical	Category name (TDS)	Group name (TDS)	Monitoring recommendation title	Monitoring recommendation category description	Monitoring recommendation indicative value (where relevant)	Units	Policy flag total
Acrylamide	Breakfast cereals	Cornflakes	Commission Recommen-dation 2013/647/ EU on investiga-tions into levels of acrylamide in food	Breakfast cereals (excluding porridge) – maize, oat, spelt, barley and rice-based products	200	µg/kg	0.2

Table 10 illustrates that there is a legislative limit applicable to aflatoxin B1 in dried figs. Furthermore, there are safeguard measures also applicable to aflatoxin B1 in dried figs, i.e. Commission Implementing Regulation (EU) No 884/2014. Therefore, in this example, aflatoxin B1 in dried figs is assigned a policy flag of 0.11.

Table 10: Aflatoxin B1 in dried figs

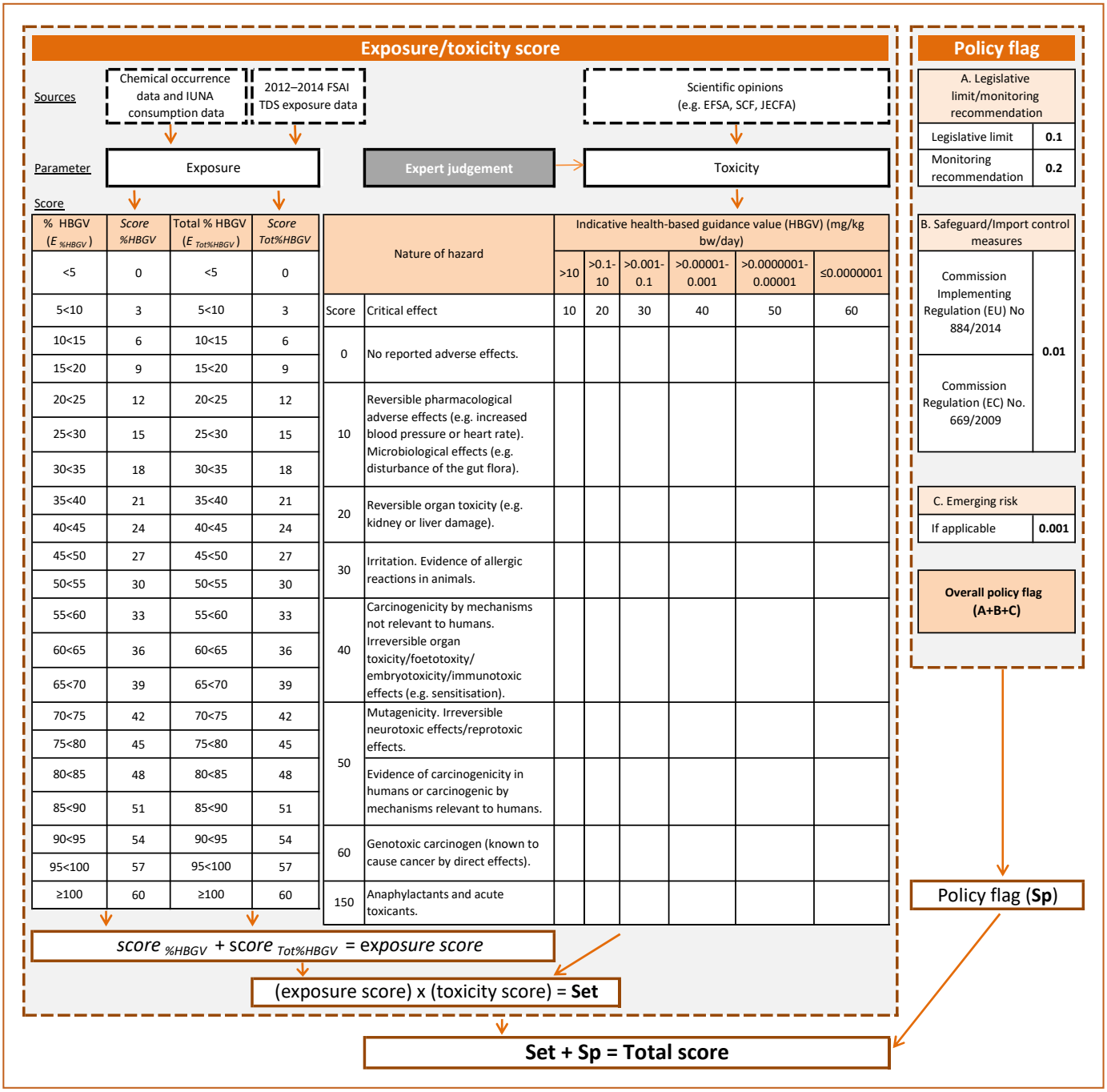
Chemical	Category name (TDS)	Group name (TDS)	Regulation (EC) No. 1881/2006	Legislative limit	Units	Legislative limit flag	Regulation (EU) No 884/2014	Country of origin	Safeguard regulations flag	Policy flag total
AFB1	Dried fruit	Dried fruit excl. raisins	Dried figs	6.0	µg/kg	0.1	• Dried figs • Mixtures of nuts or dried fruits containing figs • Fig paste • Figs, prepared or preserved, including mixtures	Turkey	0.01	0.11

The incorporation of a numerical decimal flagging system was found to work well, as this format was consistent with the exposure and toxicity scores, which are both numerical. However, other options which may be explored for the policy flag include a colour coding system or symbols.

4.4 Risk Ranking Model (summary)

Figure 1 provides a visual representation of the integration of the exposure score, toxicity score and policy flag. As shown in the diagram, equal weights are assigned to the exposure score and the toxicity score, whereas the policy flag is incorporated in the form of a decimal flagging system (no weight assigned).

Figure 1. Overview of the FSAI Risk Ranking Model



CHAPTER 5. PILOT STUDY

Using the approach outlined in Figure 1, the four case studies: acrylamide, aflatoxin B1, cadmium and fumonisin B1 were ranked. The top four results generated from the risk ranking approach for acrylamide, aflatoxin B1, cadmium and fumonisin B1 (FB1) are shown in Table 11. As detailed in the 2012–2014 TDS Report (FSAI, 2016), fusarium toxins were not detected in any of the samples tested, as the limits of detection (LODs) were relatively high (20 µg/kg for fumonisins). Therefore, the resulting exposure score for fumonisin B1, based on lower bound values, was zero. In accordance with the approach outlined in Figure 1, the exposure score is multiplied by the toxicity score. Therefore, in order to retain the toxicity score for chemical/foodstuff combinations which have an exposure value of zero, the overall exposure score in such cases was given a default value of 1.

Table 11. Risk ranking output for four chemicals in the pilot study

Chemical	Category name (TDS)	Group name (TDS)	Exposure score total	Toxicity score total	Policy flag	Total score
aflatoxin B1	Fine bakery ware	Other cakes buns and pastries	120	120	0	14,400
aflatoxin B1	Pizza	Pizza tomato and cheese	120	120	0	14,400
aflatoxin B1	Fine bakery ware	Plain biscuits	120	120	0	14,400
aflatoxin B1	Fine bakery ware	Chocolate biscuits	120	120	0	14,400
acrylamide	Snacks	Crisps	120	80	0.2	9,600.2
acrylamide	Fine bakery ware	Plain biscuits	120	80	0.2	9,600.2
acrylamide	Potatoes	Chips, homemade from frozen pre-prepared	120	80	0.2	9,600.2
acrylamide	Breakfast cereals	Wheat-type cereals	102	80	0.2	8,160.2
cadmium	Milk and cream	Low-fat, skimmed and fortified milks	27	90	0	2,430
cadmium	Fresh vegetables	Lettuce	24	90	0.3	2,160.3
cadmium	Potatoes	Potatoes without skin (boiled)	24	90	0.3	2,160.3
cadmium	Fresh vegetables	Carrots (boiled)	24	90	0.3	2,160.3
FB1	Breakfast cereals	Cornflakes	1	50	0.1	50.1
FB1	Wheat flour	White flour	1	50	0	50
FB1	Fine bakery ware	Other cakes buns and pastries	1	50	0	50
FB1	Herbs and spices	Herbs	1	50	0	50

An example of how the overall output score was generated for acrylamide in crisps (i.e. 9,600.2 in Table 11) is shown below. The same approach was used for all of the case studies analysed.

Exposure score:

$$\frac{\text{Exposure to acrylamide in crisps (0.038 µg/kg bw/day)}}{\text{(indicative) HBGV (0.017 µg/kg bw/day}^{3}\text{)}} \times 100 = E_{\%HBGV}\ (224.6\%)$$

$$\frac{\text{Exposure to acrylamide from all foods (0.165 µg/kg bw/day)}}{\text{(indicative) HBGV (0.017 µg/kg bw/day)}} \times 100 = E_{Tot\%HBGV}\ (971.4\%)$$

score $E_{\%HBGV}$ (score of 60) + score $E_{Tot\%HBGV}$ (score of 60) = exposure score (score of 120)

Toxicity score:

Nature of hazard

Epidemiological associations have not demonstrated that acrylamide is a human carcinogen. The reference point of 0.17 mg/kg bw/day was derived by EFSA as the lowest $BMDL_{10}$ from data on incidences of Harderian gland adenomas and adenocarcinomas in male mice exposed to acrylamide for two years (EFSA CONTAM Panel, 2015). Therefore, acrylamide was considered to elicit carcinogenicity by mechanisms not relevant to humans (score of 40).

(Indicative) HBGV

0.017 µg/kg bw/day (0.000017 mg/kg bw/day) (score of 40)

nature of hazard score (score of 40) + (indicative) HBGV score (score of 40) = toxicity score (score of 80)

Policy flag:

There is a Commission Recommendation (2013/647/EU) in place for acrylamide, with an indicative level of 1000 µg/kg applicable to potato crisps. Therefore, the decimal flag of **0.2** was assigned to acrylamide.

Total score for acrylamide in crisps:

(exposure score (120) x toxicity score (80)) + policy flag (0.2) = 9,600.2

[3] $BMDL_{10}$ of 0.17 mg/kg bw/day for neoplastic effects in mice ÷ 10,000=0.017 µg/kg bw/day (indicative HBGV)

CHAPTER 6. RECOMMENDATIONS

1. The FSAI should pilot the proposed model for a minimum period of two years, after which it should be presented to the Scientific Committee for review.

2. Existing data from the most recent TDS and other full dietary exposure assessments (e.g. dioxins) should be utilised to progress the ranking for as many food/chemical combinations as possible. However, as previously mentioned, some improvements in the data capture systems will be required (i.e. harmonisation of food consumption, concentration data and applicable provisions laid down in legislation) to fully maximise the approach.

3. If the use of TDS exposure data is considered to be the most suitable for the risk ranking approach, future TDSs might need to be adapted to cover a wider range of both chemicals and foods. Alternatively, the National Chemical Monitoring Programme needs to be extended to generate chemical concentration data for those foods where data gaps currently exist.

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APPENDIX I: LIST OF CHEMICALS TO BE INCLUDED IN THE DEVELOPED RISK RANKING APPROACH[4]

Mycotoxins

- aflatoxins (B1, B2, G1, G2, M1)
- ochratoxin A
- zearalenone
- dexoynivalenol
- fumonisins
- T-2 and HT-2
- other tricothecenes
- modified mycotoxins (masked)
- patulin
- citrinin
- sterigmatocystein (STC)
- alternaria toxins (altenuene, alternariol, alternariol monomethyl ether, tenuazonic acid, tentoxin)
- ergot alkaloids (ergotamine, ergocornine, ergocristine, ergosine, ergocryptine, ergometrine and their corresponding 'inines')

Plant toxins

- tropane alkaloids (atropine and scopolamine)
- pyrrolizidine alkaloids (PAs) (senecionine (Sc), senecionine-N-oxide (ScN), seneciphylline (Sp), seneciphylline-N-oxide (SpN), monocrotaline (Mc), monocrotatline-N-oxide (McN), retrorsine (Re), heliotrine (Hn), heliotrine-N-oxide (HnN), trichodesmine (Td), retrorsine-N-oxide (ReN), echimidine (Em), echimidine-N-oxide (EmN), intermedin (Im), intermedin-N-oxide (ImN), lycopsamine (La), lycopsamine-N-oxide (LaN), erucifoline (Er), erucifoline-N-oxide (ErN), senecivernine (Sv), senecivernine-N-oxide (SvN) jacobine (Jb), jacobine-N-oxide (JbN), lasiocarpine (Lc), lasiocarpine-N-oxide (LcN), europine (Eu), europine-N-oxide (EuN), senkirkine (Sk), echinatine, echinatine-N-oxide, heliosupine, heliosupine-N-oxide, integerrimine and integerrimine-N-oxide, jacoline, and jaconine
- opium alkaloids (morphine, thebaine, codeine, noscapine, oripavine and papaverine)
- erucic acid
- cyanogenic glycosides: amydalin and prunasin, linamaarin, linustain, and neolinustain
- tetrahydrocannabinol (THC), delta-9-tetrahydrocannabinol, delta-9-tetrahydrocannabinolic acid, delta-8-tetrahydrocannabinol, cannabinol, cannabidiol, delta-9-tetrahydrocannabivarin, canabidivarin, cannabidiolic acid, cannabigerolic acid, cannabigerol, and cannabichromene

Metals

- tin
- cadmium
- lead
- mercury
- arsenic
- nickel

Other environmental and bio-contaminants

- nitrate
- biogenic amines (histamine, etc.)
- marine biotoxins

[4] This list will need to be reviewed on an annual basis and extended as appropriate in light of legislative developments and emerging risks.

Process contaminants

- polycyclic aromatic hydrocarbons (benzo[a]pyrene, PAH4)
- acrylamide
- furan
- glycidyl fatty acid esters (GE), 3-monochloropropanediol (3-MCPD), and 2-monochloropropanediol (2-MCPD) and their fatty acid esters

Other

- perchlorate
- chlorates
- melamine and its analogues (ammeline, ammelide, cyanuric acid and cryomazine)
- monacolin K
- Sudan I-IV

Dioxins and PCBs

- dioxins (7 Dibenzo-p-dioxins ('PCDDs'), 10 Dibenzofurans ('PCDFs'))
- PCBs (12 Dioxin-like PCBs, 6 Non dioxin-like PCBs)

PFAS

- perfluorooctane sulfonylamide (PFOSA)
- perfluorobutane sulfonate (PFBS)
- perfluorohexane sulfonate (PFHxS)
- perfluorooctane sulfonate (PFOS)
- perfluorohexanoic acid (PFHxA)
- perfluoroheptanoic acid (PFHpA)
- perfluorooctanoic acid (PFOA)
- perfluorononanoic acid (PFNA)
- perfluorodecanoic acid (PFDeA)
- perfluoroundecanoic acid (PFUnA)
- perfluorododecanoic acid (PFDoA)

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